K071809 Pg 1 of 1

510(k) Summary

Submitter's name Address	Sonoma Orthopedic Products, Inc. 650 Larkfield Center, Suite C Santa Rosa, CA 95403
Phone Number Fax Number (revised)	707-526-1335 707-526-2022
Name of contact person Date summary was prepared	Charles L. Nelson, Amy Conuel Original: June 28, 2007 Revised: February 14, 2008
Proprietary name/Trade name Common Name	EnsplintR$_X$™ Intramedullary Distal Radius Fixation Device
Classification Name	Plate, Fixation, Bone 21 CFR 888.3030
Predicate Device	Wright Locon-T Radial Plate System K994061, cleared February 14, 2000 Wright Radial Nail System K040938 cleared July 1, 2004 DVO Dorsal Intramedullary nail Plate K042437, cleared Ocotber 8, 2004
Description of device	The EnsplintR$_X$™ configuration consists of a flexible implant manufactured from stainless steel.
Intended use of device/Indications	The ENSPLINT*R$_X$*™ Distal Radius System is intended to be used for the fixation of unstable distal radius fractures in which closed reduction is not suitable: • Joint destruction and/or subluxation visible on x-ray; • Osteotomy and repair of distal radius malunion with or without bone graft; • Non-displaced fractures in which the physician and patient opt for rigid stability • Transverse fractures of the distal radius with or without comminution (e.g. AO classifications A2 and A3) • Transverse fractures of the distal radius with an extension into the joint without comminution (e.g. AO classification C1); • Failed fracture fixation with or without bone graft for the types of fractures above; • The above types of fractures (i.e. AO classifications non-displaced transverse, A2, A3, and C1) in which reduction has been lost following fixation with percutaneous pins with or without an external fixator.
Comparison to Predicate Device	The EnsplintR$_X$™ has similar intended use, performance characteristics, and materials to the predicate device.
Performance Data (Non clinical)	The results of the non-clinical (bench top) laboratory testing demonstrate that the device us substantially equivalent. Clinical evaluation of the device is not required.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 21 2008

Sonoma Orthopedic Products, Inc.
% Mr. Charles L. Nelson
650 Larkfield Center, Suite C
Santa Rosa, CA 95403

Re: K071809
Trade/Device Name: ENSPLINT*Rx* Distal Radius System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: HRS, HSB
Dated: January 30, 2008
Received: January 31, 2008

Dear Mr. Nelson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K071809

Device Name: ENSPLINTR_X™ Distal Radius System

Indications for Use

INDICATIONS

The ENSPLINTR_X™ Distal Radius System is intended to be used for the fixation of unstable distal radius fractures in which closed reduction is not suitable:

- Joint destruction and/or subluxation visible on x-ray;
- Osteotomy and repair of distal radius malunion with or without bone graft;
- Non-displaced fractures in which the physician and patient opt for rigid stability
- Transverse fractures of the distal radius with or without comminution (e.g. AO classifications A2 and A3)
- Transverse fractures of the distal radius with an extension into the joint without comminution (e.g. AO classification C1);
- Failed fracture fixation with or without bone graft for the types of fractures above;
- The above types of fractures (i.e. AO classifications non-displaced transverse, A2, A3, and C1) in which reduction has been lost following fixation with percutaneous pins with or without an external fixator.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K071809